

Outline of Research Protocol

Every IRB application is to be accompanied by a detailed research protocol. This protocol must follow the outline below. If an area is not applicable, the heading should be listed followed by “Not applicable” or “None” to insure that the area was considered by the investigator.

Study Identifier

Protocol Title

The protocol title is the same as the project title provided on the FLMU-IRB submission form and on all consent forms.

Principal Investigator and Co-Investigator

List the complete name of all co-investigators. Students must include faculty adviser/thesis chair as a co-investigator.

Location of Study

All sites where data will be gathered are listed within this section. If this includes non-FMU sites, an agreement from those sites for the conduct of the study must be attached. Include the name, degree(s), title, employing institution, and complete address of the investigator(s) at each site. If the study is Internet based, the investigator should describe where data will be collected (individuals logging in from home, subjects coming to a physical site, etc.).

Purpose and Potential Benefits

This section is intended for a description of the main goals and justification for the study as well as a brief literature or historical overview pertinent to the study. Investigators should summarize the background, rationale, nature, and significance of the proposed research. It is helpful to discuss the results of previous related research. The investigator should discuss any potential benefits of the study as these relate to professional/scientific knowledge.

Subjects

This section is intended for investigators to provide details about all the proposed subjects in the study.

Sample Size and Composition

Included within this section are descriptions of the gender, ethnicities, and primary language(s) of subjects (if other than English). Justification for use of any special/vulnerable subject population should be included.

Subject Selection, Recruitment, and Eligibility Requirements

This section must include a detailed description of how subjects will be recruited, how they will be screened, and what eligibility criteria will be used. If subjects come from any entity that is covered by HIPAA, particular attention should be paid to methods that will

be used to insure patient privacy.

Any media, including flyers, brochures, or other advertisements used to recruit human subject participation in a research study, must be submitted to the IRB for review and approval and must be included as part of the IRB submission package.

This section must also provide a detailed description of the proposed informed consent process, with particular attention to the minimization of coercion and discussion of how the investigator will provide an opportunity for the prospective subject, or the legally authorized representative, to consider whether or not to participate in the study. This section should also include the circumstances surrounding language difficulties/translators, obtaining assent from minors, and using witnesses.

Methods and Procedures

This section should include all details as to what will happen to subjects throughout the study and in what order. If there is more than one study group, details should be given separately for each group. All tests or procedures should be indicated (and described more fully) in the next section. The time periods involved for all work should be provided. Provisions for managing adverse reactions are to be included. Any compensation to subjects or extra costs to subjects should be discussed. Any compensation for injured research subjects should be discussed.

Measures and Administration

This should include a paragraph or more on all tests or procedures used. If these are paper and pencil measures, a copy should be attached. A copy of all surveys or questionnaires must also be described and attached. If the procedures are not “paper and pencil,” they should be described in detail so they can be understood by an intelligent layperson.

Risks to Subjects

This section is intended for possible risks to the client. All studies must address the issue of possible loss of subject confidentiality, while other risks are unique to the specific study. Each risk should be addressed in the following format individually, with as many paragraphs as there are risks to the study.

- Risk: List each risk individually
- Likelihood: Usually classified as minimal, moderate, or high.
- Magnitude/Duration
- Minimization: These are procedures undertaken to minimize the risk that this specific risk poses.

Investigators should be sure to discuss all potential risks, discomforts, hazards, or inconveniences of the research study. Some possible risks include physical pain or discomfort, psychological or emotional harm, invasion of privacy, and loss of time or pay. Some studies, due to the nature of the population, present risks to a community or group of individuals. These risks must also be addressed.

Benefits to Subjects

This section is intended for all direct benefits of the study to participants. This does not usually include “helping research” or other generalities, nor does it include compensation for participation. Some examples of benefits include: receiving free treatment, receiving a list of reputable local services, tutoring skills, or an informed debriefing. The value of any such benefits should be listed as well. If there are no direct benefits to the participants, this should also be indicated.

Risk/Benefit Ratio

An overall analysis of the risks of the study to the benefits received by the subject as well as the general benefits of the study itself to science research should be discussed. The review of risks to benefits is a key element in IRB review.